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1634
JW #IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. 08/887,505 Art Unit: 1634
Applicant: Kilkuskie *et al.* Examiner: Diana B. Johannsen
Date Filed: July 2, 1997 Conf. No.: 1117
Docket No.: HYZ-040CIP Cust. No.: 23483
Title: **Oligonucleotides Specific for Hepatitis C Virus**

CERTIFICATION UNDER 37 C.F.R. § 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" Service under 37 C.F.R. § 1.10 on the date indicated below and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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RESPONSE TO SPECIES ELECTION PURSUANT to 35 U.S.C. § 121

Sir:

In the Office Action of *July 1, 2004* (hereinafter "Office action"), the Examiner alleged that the application contains claims directed to the following patentably distinct species of the claimed invention:

- (a) The synthetic oligonucleotides sequences disclosed as being complementary to the 5'UTR of hepatitis C virus as set forth in claim 1; and
- (b) The synthetic oligonucleotides sequences disclosed as being complementary to non-contiguous regions of an HCV messenger or genomic RNA.

The Examiner required that Applicants elect a single species from the SEQ ID NOs disclosed in (a), and a single species from the SEQ ID NOs encompassed by (b).

Accordingly, Applicants provisionally elect, with traverse, the species of SEQ ID NO: 28 for (a); and SEQ ID NO: 38 from the sequences encompassed by (b). Election of SEQ ID NO:28 reads on claims 1, 4, 8,-20, 25, 27-28, 30, 42, and 44. Election of SEQ ID NO: 38 reads on claims 2, 4-22, 25, 27, 28, 30, 42, 43 and 45. In addition, Applicants note that the Examiner has not required election of a species for claim 3. Nevertheless, to expedite prosecution, Applicants provisionally elect SEQ ID NO: 148. Applicants gratefully note that the sequence of claim 46 (SEQ ID NO:117) will also be searched, and that claim examined. Applicants' substantive arguments in support of their traversal of the species election requirement are presented below.

At the outset, it is noted that when the instant application was originally filed, the Examiner who first examined this case (Examiner Joyce Tung) restricted the claims into three groups (*see*, Appendix A). Group I consisted of claims drawn to a synthetic oligonucleotide complementary to a portion of the 5' untranslated region of the hepatitis C virus, classified in class 536, subclass 23.1 or 24.3. Group I claims consisted of essentially the same claims as those that are currently pending in the instant application. The previous Examiner did not require a species election, either in making the Restriction Requirement, or throughout the prosecution of the application. Thus, Applicants respectfully contend the United States Patent and Trademark Office has previously determined (implicitly) that it would not pose an undue burden to examine the currently pending claims without a species election. Furthermore, Applicants respectfully assert that it would also not be unduly burdensome for the Examiner to search all the claimed species of synthetic oligonucleotides in the instant application as they all relate to the hepatitis C virus.

However, even if the Examiner were to consider the examination of the present claims to be unduly burdensome, Applicants note that MPEP § 803.04 states that "the Commissioner has decided *sua sponte* to...permit a *reasonable number* of nucleotide sequences to be claimed in a single application...(and that)....it has been determined that normally *ten* sequences constitute a reasonable number for examination purposes" (emphases added). This section of the MPEP

goes on to state that "in some *exceptional* cases, the complex nature of the claimed material, for example a protein amino acid sequence reciting three dimensional folds, may necessitate that the reasonable number of sequences to be selected be less than ten" (emphasis added).

The instant Restriction Requirement states only that "the large number of individual sequences encompassed by the claims necessitates this requirement, as the claims as now written cannot be searched and examined without posing a serious burden."

Applicants respectfully note that, first, the synthetic oligonucleotide sequences in question are only about 12-32 nucleotides in length and are readily searchable using the computer algorithms and sequence databases available to the P.T.O., so that it is unclear upon what basis the assertion that the search poses a serious burden rests. Applicants further note that, even if the search were "complex" in nature, MPEP § 803.04 does not state that this is an issue in examining multiple sequences, rather it states that the complexity of the claimed material may be an issue in some exceptional cases, however the sequences claimed are not complex and a justification for their exceptional treatment has not been presented.

Furthermore, Applicants note that the mere fact that the sequences "each have a unique nucleotide sequence" is not dispositive to whether it would be an undue burden to examine them together. This is particularly true in the instant case where a simple search for all possible hepatitis C virus antisense sequences could be conducted simply and efficiently by using straightforward search strings using the known hepatitis C nucleotide sequence. In view of these points, Applicants respectfully urge reconsideration of the species election requirement and withdrawal of the requirement to elect a single synthetic oligonucleotide sequence from each of (a) and (b) described above.

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CONCLUSION

In summary, Applicants have provisionally elected, with traverse, the species of SEQ ID NO: 28 for (a) and the species of SEQ ID NO: 38 for (b). In addition, with respect to claim 3, Applicants provisionally elect SEQ ID NO: 148. Applicants respectfully urge reconsideration and withdrawal of the species election requirement. Further and favorable consideration on the merits of the claims of record is also respectfully requested at this time.

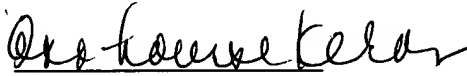
Applicants petition for a One Month Extension of Time, up to and including September 1, 2004. Please charge the requisite fee to our Deposit Account No. 08-0219.

No additional fees are believed to be due in connection with this correspondence; however, if any fees are due, please charge the payments due to our Deposit Account No. 08-0219.

If a telephone interview would advance prosecution of the application, the Examiner is invited to telephone the undersigned at the telephone number given below.

Respectfully submitted,

Dated: August 25, 2004


Ann-Louise Kerner, Ph.D.
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